

**SUMMARY OF THE  
ON-SITE ASSESSMENT COMMITTEE MEETING  
JULY 18, 2001**

The On-site Assessment Committee of the National Environmental Laboratory Accreditation Conference (NELAC) met by teleconference on Wednesday, July 18, 2001 at 1:00 p.m. Eastern Daylight Time (EDT). The meeting was led by its chair, Mr. Alfredo Sotomayor of the Wisconsin Department of Natural Resources. A list of action items is given in Attachment A. A list of participants is given in Attachment B. *The purpose of the meeting was to address items of importance as identified in the committee's previously distributed meeting agenda.*

**INTRODUCTION**

Mr. Sotomayor called the meeting to order with a review of the minutes of the committee's June 27 teleconference. The minutes were approved as written. Mr. Sotomayor then made several brief announcements. Noting that he had distributed the committee's membership roster for review, he asked that committee members notify him via e-mail of any changes in contact information. Mr. Sotomayor also noted that he had recently received the 2001 NELAC Standard for review. He anticipated that he would finish his review within the next few days and noted that he had made only minor corrections in the document. Mr. Sotomayor's final announcement directed participants' attention to a document available on the U.S. Environmental Protection Agency's (EPA) Website. Mr. Sotomayor noted that he had received the peer review draft of a document, entitled *Guidance on Environmental Data Verification and Data Validation* (EPA-QA/G8). He indicated that the document contains information that the committee may find useful as they address the issue of data validation.

**STATUS OF ACTION ITEMS**

Mr. Sotomayor updated participants on the status of action items from the committee's June 27 teleconference as follows:

- **Mechanism for recognizing departing committee members** - Mr. Sotomayor reported that he had communicated via e-mail with Ms. Jeanne Hankins, NELAP Director, Ms. Silkie Labie, NELAC Chair, and the NELAC Membership and Outreach Committee regarding mechanisms for recognizing departing committee members for their contributions. Mr. Sotomayor learned that, aside from a letter of thanks from the committee or a letter of thanks from the NELAC Chair written at the request of the committee, there is no official NELAP mechanism to recognize departing members. Noting that the NELAC Board of Directors (BoD) routinely sends new committee members an official letter of appointment, the committee agreed to recommend that the BoD routinely issue a certificate of recognition or letter of thanks to departing committee members. Mr. Sotomayor indicated that he would write to Ms. Labie to make this recommendation to the BoD on behalf of the On-site Assessment Committee.
- **Microbiology expertise outside the On-site Assessment Committee to draft subgroupings for technical training** - Mr. Sotomayor reported that he had contacted Ms. Sharon Kleunder of the Wisconsin State Laboratory of Hygiene. Ms. Kleunder also

serves on the NELAC Quality Systems Appendix D3 Microbiology Subcommittee. She agreed to lend her expertise to the On-site Assessment Committee but wanted to consult with the subcommittee on the subgroupings during their next meeting in August.

- **Expanded language on “Data Document and Review” in Appendix A** - on July 18 agenda
- **Continued development of Appendix C** - on July 18 agenda
- **Review of Chapter 3 for consistency with other chapters** - on July 18 agenda
- **Update of Chapter 5 assessment checklist** - on July 18 agenda
- **Coordination with Accrediting Authority Workgroup on minimum elements of an on-site assessment** - on July 18 agenda
- **Continued development of Appendix D** - discussion deferred to a future teleconference

## **APPENDIX A**

Mr. Sotomayor led participants in a discussion of data and document review as addressed in Appendix A, Section A.4.11.2.3 (On-site Assessment Proper). He reminded participants of previous discussions in which committee members suggested using a relatively simple chemistry methodology, such as pH, as a “universal example” for data review and asked if this past approach was reasonable. Some participants suggested that pH would be too simple. It was noted that Appendix A as written does not preclude any training provider from using this approach. There was moderate discussion of whether Appendix A should provide clarification in requiring a specific training approach to data and document review. It was suggested that clarifying language such as “including quality control (QC) criteria” be added to the data document and review item. Ms. Marlene Moore volunteered to draft clarifying language for review at the committee’s next teleconference.

## **MINIMUM ELEMENTS OF ON-SITE ASSESSMENT**

Mr. Sotomayor reported that he had communicated with Mr. Richard Sheibley and Dr. Ken Jackson regarding efforts to develop minimum elements to be reviewed during an on-site assessment. Mr. Sotomayor reported that Mr. Sheibley had agreed to act as the On-site Assessment Committee’s liaison to the Accrediting Authority Workgroup. Mr Sotomayor also reported that Dr. Jackson had explained that the Accrediting Authority Workgroup has established a subcommittee to address the issue. Dr. Jackson informed Mr. Sotomayor that the subcommittee was attempting to clarify what is involved in reviewing methods and records on-site. Dr. Jackson reported that the subcommittee is in agreement that all methods must be reviewed. In response to participants’ questions, Mr. Sotomayor reported that he was not sure whether “method” refers to standard operating procedure (SOP) or mandated test method because the subcommittee does not yet have a final work product. He reported that Dr. Jackson anticipates having a final work product by late July or early August. Mr Sotomayor also reported that it is his understanding that the work product will be forwarded to the On-site Assessment Committee in the form of a recommendation. The On-site Assessment Committee

must then decide whether to revise the standard to include the Accrediting Authority Workgroup's recommended language. Mr. Sotomayor asked for committee input on how to proceed. Participants initially expressed their concern that the issue might be allowed to languish. In response Mr. Sotomayor noted that Dr. Jackson had assured him that the work product was almost complete. After moderate discussion in which it was noted that the workgroup's effort would do much to ensure consistency of assessments, participants agreed that the On-site Assessment Committee should table discussion of the issue pending a review of the Accrediting Authority Workgroup's recommendations.

## **APPENDIX C**

Mr. Sotomayor briefly reviewed comments received on Appendix C at NELAC 7. Committee discussion focused on pre-assessment document review, confidential business information (CBI) issues, and report release.

**Pre-Assessment - Item 3 - Document Review** – It was suggested that preliminary findings should be presented during the opening conference so that the laboratory has the opportunity to provide additional information to resolve or reconcile the findings while the assessment team is on-site. A member noted that the International Organization for Standardization (ISO) and American Association for Laboratory Accreditation (A2LA) require that assessors provide the laboratory with a written report of the preliminary document review prior to the assessment. One participant indicated that he routinely performs the pre-assessment document review shortly before the assessment so that the review is still fresh in his mind during the assessment. It was agreed that the assessment team must make a distinction between minor preliminary findings and major findings requiring the postponement of the assessment. It was noted that Appendix C as written neither requires nor prohibits the presentation of preliminary findings to the laboratory by the accrediting authority. The committee agreed that the sentence referring to the presentation of preliminary findings should be rewritten as follows:

The accrediting authority shall present preliminary findings either before the on-site assessment or at the opening conference.

**Pre-Assessment - Item 5 - CBI** – It was noted that Appendix C as written references federal CBI regulations only. There was a brief discussion of whether this reference presents a problem for states bound by their own CBI regulations. Mr. Sotomayor noted that the issue raised at NELAC 7 had been one of consistency. Appendix C and Chapter 3 (Section 3.4.5) must be in agreement. The issue was tabled for further discussion at a future teleconference.

**Assessment Reporting- Item 3 - Report Release** – Noting that assessment reports will not be included in the national database, participants first discussed deleting this section's allusion to the national database and leaving the remainder of the section as written. This led to extensive discussion of whether assessment reports may be considered public information. It was suggested that what may be considered public information depends upon state Freedom of Information Act (FOIA) law. One participant noted that A2LA has strict confidentiality requirements. Another participant noted that his state has a very liberal public information law. A third participant expressed the opinion that the issue is not pertinent to laboratory accreditation and, therefore, is not a NELAC issue. It was agreed that, while Chapter 3 (Section 3.7.4) addresses the release of assessment reports, Appendix C stipulates that the accrediting authority

must include the issue in its SOP for on-site assessments. The committee agreed that the section should be rewritten as follows:

The SOP describes the requirements for release of the assessment report to the laboratory. The SOP shall also describe how requests for assessment reports will be addressed.

As discussion of Appendix C ended, Mr. Sotomayor indicated that he would provide Ms. Mimi Uhlfelder with the language revisions drafted by the committee.

### **CHAPTER 3 CONSISTENCY REVIEW**

Participants agreed to assign each chapter of the 2001 NELAC Standard to one committee member for review for consistency against Chapter 3. Participants also agreed that the entire committee should review Chapter 5. The strategy suggested for the review was to scan each chapter, when published, for mention of “trigger” words or phrases, such as “Chapter 3,” “on-site,” or “assessment.” Committee assignments were made as follows:

- Chapter 1 – Mr. Jack Hall
- Chapter 2 – Mr. Faust Parker
- Chapter 4 – Mr. Sheibley
- Chapter 5 – All
- Chapter 6 – Mr. Santos Urrea

### **CHAPTER 5 CHECKLIST UPDATE**

Noting that Mr. Charles Dyer had once again agreed to lead the effort to update the Chapter 5 assessment checklist, Mr. Sotomayor invited him to lead discussion of the checklist. Mr. Dyer pointed out that most accrediting authorities will have to use the 1999 checklist associated with the 1999 NELAC Standard for another year. The 1999 checklist must be reviewed and minor clarifications made to remove ambiguity. Mr. Dyer reported that he hoped to have completed this task by the end of July. Noting that states may wish to accredit laboratories to the 2001 NELAC Standard before 2003, as allowed in the NELAC Operating Policy on Effective Date of Implementation of the Standards (item 3), Mr. Dyer indicated that the 2000 checklist had to be reviewed and updated for consistency with the 2001 NELAC Standard. He noted that he had never received committee approval on the 2000 checklist and would, therefore, distribute the 2000 checklist for committee review by the end of the week. Mr. Dyer indicated that he would obtain an electronic copy of the 2001 (Chapter 5) Quality Systems Standard to save retyping. He reported that he had spoken to Dr. Fred Siegelman about this issue at NELAC 7.

### **CONCLUSION**

The committee’s allotted teleconference time having expired, Mr. Sotomayor thanked everyone in attendance for their input. The meeting was adjourned at 2:30 p.m. EDT. The committee’s next meeting will be on August 1, 2001 via teleconference.

**ACTION ITEMS**  
**ON-SITE ASSESSMENT COMMITTEE MEETING**  
**JULY 18, 2001**

<b>Item No.</b>	<b>Action</b>	<b>Date to be Completed</b>
1.	Mr. Sotomayor will write to Ms. Labie on behalf of the On-site Assessment Committee to recommend that the BoD adopt a policy of routinely recognizing departing NELAC committee members with a certificate or letter of thanks.	8/1/01
2.	Ms. Moore will draft clarifying language for “Data and Document Review” (Appendix A, Section A.4.11.2.3, item 5).	8/1/01
3.	Mr. Sotomayor will provide Ms. Uhlfelder with a copy of Appendix C language revisions discussed in the committee’s July 18 teleconference.	7/27/01
4.	Committee members will review 2001 NELAC Standard for consistency with Chapter 3 as follows: <ul style="list-style-type: none"> <li>• Chapter 1 – Mr. Hall</li> <li>• Chapter 2 – Mr. Parker</li> <li>• Chapter 4 – Mr. Sheibley</li> <li>• Chapter 5 – All</li> <li>• Chapter 6 – Mr. Urrea</li> </ul>	10/1/01
5.	Mr. Dyer update Chapter 5 assessment checklist to remove ambiguity and reflect recent changes to the NELAC Standard as follows: <p>Task 1 -- Clarify/correct 1999 checklist to remove ambiguity</p> <p>Task 2a -- Distribute 2000 checklist for committee review and approval</p> <p>Task 2b – Update 2000 checklist for consistency with 2001 NELAC Standard</p>	<p>7/31/01</p> <p>7/27/01</p> <p>10/1/01</p>
6.	Committee will meet via teleconference.	8/1/01

**PARTICIPANTS**  
**ON-SITE ASSESSMENT COMMITTEE MEETING**  
**JULY 18, 2001**

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